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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,944	03/22/2001	Keith D. Allen	R-654	8251

26619 7590 06/03/2004

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EXAMINER	
QIAN, CELINE X	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/815,944	ALLEN ET AL.	
	Examiner	Art Unit	
	Celine X Qian	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30,32 and 33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30,32 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 March 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 30, 32 and 33 are pending in the application.

This Office Action is in response to the amendment filed on 3/22/04.

Response to Amendment

The rejection of claims 26, 28, 29 and 35 under 35 U.S.C. 103 (a) is moot in light of Applicant's cancellation of the claims.

The rejection of claim 30 under 35 U.S.C. 112 2nd paragraph has been withdrawn in light of Applicant's amendment of the claim.

Claims 30, 32 and 33 are rejected under 35 U.S.C. 112 1st paragraph for reasons discussed below.

New Grounds of Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 30, 32 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (a) the nature of the invention; (b) the breadth of the claims; (c) the state of the prior

art; (d) the amount of direction provided by the inventor; (e) the existence of working examples; (f) the relative skill of those in the art; (g) whether the quantity of experimentation needed to make or use the invention based on the content of the disclosure is "undue"; and (h) the level of predictability in the art (MPEP 2164.01 (a)).

Nature of the Invention:

Claims 30, 32 and 33 are drawn a transgenic mouse comprising a disruption in a melanocyte stimulating hormone receptor gene, wherein the disruption is homozygous, the mouse does not produce functional melanocyte stimulating hormone receptor protein, and exhibits phenotype of hypoactivity. The claims are further drawn to a cell or a tissue isolated from said transgenic mouse, and a method of producing said transgenic mouse.

Breadth of claims and amount of guidance in the specification and working Examples:

In the instant case, claims 30, 32 and 33 encompass a transgenic mouse that exhibits hypoactivity. The specification does not provide an enabling disclosure for how to use the transgenic mouse as claimed. The specification discloses a melanocyte stimulating hormone receptor transgenic knockout mouse, wherein the homozygous knockout mouse exhibits phenotype of hypoactivity measured by the open field test. The specification does not provide specific teaching on how to use these mice with the disclosed phenotype. The specification prophetically teaches that the transgenic mouse can be used to screen drugs or as models for diseases, or screening agents that modulates a phenotype of said mouse. However, the specification fails to teach what type of diseases are the disclosed phenotypes related to. The specification also fails to teach how to use the agent that modulates the phenotype associated with melanocyte stimulating hormone receptor gene disruption. As such, one skilled in the art

would not know how to use the transgenic mouse with phenotype of hypoactivity as a disease model or screen drugs for a specific disease. Moreover, the specification fails to teach how to use a cell or tissue isolated from the transgenic mouse. Therefore, the teaching of the specification is limited.

The state of art and the predictability in the art

The state of art at the time of filing considers generating null mutation of a specific gene in mice and phenotypic behavior resulted from the mutation is unpredictable. Crawley et al. (1997, Psychopharmacology, Vol 132, pages 107-124) teaches that the phenotype of a mutant mouse is not only the result of the targeted gene, but it also reflects interactions with background gene, and other unknown mutations in the genetic background (see pages 107 last paragraph through page 108 1st paragraph). The article further teaches that not all isogenic backgrounds are appropriate for a given study, since the behavioral characteristics of certain isogenic strains could overshadow the effects of the targeted mutations (see page 108, 1st col., lines 10-14). Furthermore, it points out that no single behavior commonly measured in the open field appears to reflect only anxiety or emotional reactivity. Moreover, two strains commonly used in ES cell and knockout generation C57BL/6 and various substrains of 129 are unusual on many standard behavioral paradigms. The unique traits of 129 and C57BL/6 mice are examples of a widespread problem for interpretation of behavioral phenotypes of null mutations, given the genetic diversity that exists amongst the dozens of other commonly available inbred mouse strains (see page 108, 2nd paragraph). Therefore, whether the phenotype of hypoactivity is result from null mutation alone is unpredictable.

The state of art at the time of the filing is silent on a transgenic mouse whose genome comprises a disruption in an endogenous melanocyte stimulating hormone receptor gene, wherein the disruption is homozygous, said mouse lacks production of the melanocyte stimulating hormone receptor protein, and said mouse exhibits phenotypic feature of hypoactivity, as compared to a wild type mouse. The art does not provide any teaching regarding the relationship between melanocyte stimulating hormone receptor function and hypoactivity. The art is also silent on what type of disease is related to melanocyte stimulating hormone receptor dysfunction that would result in the disclosed phenotype. As such, whether transgenic mouse exhibits phenotype of hypoactivity can be used for a disease model or screening for drugs is unpredictable. One skilled in the art would have to engage in undue experimentation to use the invention as claimed. Therefore, the claimed invention is not enabled by the instant specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine Qian, Ph.D.